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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,382	12/29/2000	Jon M. Bishay	33734-8004US1	7499
7590	10/29/2003		EXAMINER	
BLANK, ROME, LLP 600 New Hampshire Avenue, N.W. Washington, DC 20037			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	
			DATE MAILED: 10/29/2003	

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/751,382	BISHAY ET AL.
	Examiner	Art Unit
	George R Evanisko	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  
 - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 9/2/03.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 4-6,8,23,24,28,29,33,36-40,42-63,65-75,77-84,87-92 and 131-133 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 29,52,55,60,67,72,77-82 and 88 is/are allowed.

6) Claim(s) See Continuation Sheet is/are rejected.

7) Claim(s) 84 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

Continuation of Disposition of Claims: Claims rejected are 4-6,8,23,24,28,33,36-40,42-51,53,54,56-59,61-63,65,66,68-71,73-75,83,84,87,89-92 and 131-133.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6, 8, 13, 23, 24, 28, 32, 33, 36, 38-40, 42-44, 47, 49, 53, 54, 58, 61-63, 65, 66, 70, 83, 87, 89, 91, 92 and 131-133 are rejected under 35 U.S.C. 102(b) as being anticipated by Varelis et al. (5033474). Varelis is capable of meeting the functional use recitations presented in the claim. Varelis's system uses a laptop ("configured to rest on a body") and uses hooks, clips, and snap type fasteners, ("configured to be coupled to a percutaneous probe"). In addition, "cavity" is a broad term and met by Varelis since he uses holes, hollows, deeply indented or concave areas, etc. on the support member or engagement member.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37, 45, 46, 48, 50, 51, 56, 57, 59, 68, 69, 71, 73-75, 83, and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varelis et al.

Varelis discloses the claimed invention and being able to use different fasteners for the cables except for the support member being flexible, biocompatible, and resilient to conform to a surface of the body (claims 37, 48, and 90), the engagement members having different colors or visual indicators (claims 45 and 46), the first coupler including a conductive clamp or alligator clip (claims 50, 51, 56, 57, 68, and 69), and the cables being different lengths (claims 59 and 71). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the health system as taught by Varelis, with the support member being flexible, biocompatible, and resilient to conform to a surface of the body, the first coupler including a conductive clamp or alligator clip, and the cables being different lengths, since it was known in the art that health systems use: support members that are flexible, biocompatible, and resilient to conform to a surface of the body, the cables being different lengths, to provide a comfortable support member that does not irritate the patient; the engagement members having different colors or visual indicators to prevent a mix-up of electrodes or cables and to show where electrodes or cables should be attached to the patient; the first coupler including a conductive clamp or alligator clip to provide an equivalent alternative fastener to allow the parts to be quickly and easily connected and disconnected; and cables that are different lengths to allow the

electrodes to reach places on the patient at a distance further from other electrodes that do not require that distance.

***Response to Arguments***

Applicant's arguments filed 9/2/03 have been fully considered but they are not persuasive. The argument that Varelis does not aid in the placement of the couplers is not persuasive since Varelis's system aids in the placement of the couplers back into the monitor for storage (the claim does not state "aids in the placement of the couplers on the patient"). In addition, Varelis states in column 3 that the system is used to "prevent entanglement of ECG cables when in use" and therefore will meet the claim limitation of "aids in the placement of the couplers". Finally, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The argument that the applicants "monitoring" is referring to monitoring of "stimulation treatment" parameters and therefore Varelis will not meet the claimed limitations is not persuasive since the features upon which applicant relies (i.e., monitoring of stimulation parameters) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, in response to applicant's arguments, the recitation of "monitoring" has not been given patentable weight because the

recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In addition, even if the monitoring was added to the claim body, Varelis would still be capable of meeting the functional use recitations presented in the claims.

***Allowable Subject Matter***

Claims 29, 52, 55, 60, 67, 72, 77-82, and 88 are allowed.

Claim 84 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

*GE*  
George R Evanisko  
Primary Examiner  
Art Unit 3762

*10/28/03*

GRE  
October 28, 2003